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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.            |
|--|-------------|----------------------|---------------------------------|-----------------------------|
| 10/528,311   | 03/24/2006  | Richard F. Ambinder  | 43369-103949                    | 2676                        |
| 23644 7590 03/25/2008<br>BARNES & THORNBURG LLP<br>P.O. BOX 2786<br>CHICAGO, IL 60690-2786 |             |                      | EXAMINER<br>LI, BAO Q           |                             |
|  |             |                      | ART UNIT<br>1648                | PAPER NUMBER                |
|  |             |                      | NOTIFICATION DATE<br>03/25/2008 | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent-ch@btlaw.com

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/528,311 | <b>Applicant(s)</b><br>AMBINDER ET AL. |  |
|                              | <b>Examiner</b><br>Bao Qun Li        | <b>Art Unit</b><br>1648                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims filed on March 17, 2005 have been acknowledged. Claims 1-57 are pending.

#### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13, 16-49, drawn to a human cell line expressing an EBV gene and an immunomodulatory gene.

Group II, claim(s) 14, 50-53, drawn to a composition and a method for using the composition comprising one human cell line expressing immunomodulatory gene and another human cell line expressing a nucleotide sequence encoding an antigen of EBV.

Group III, claim(s) 15, 54-57, drawn to a composition and a method of using the composition comprising an immunomodulator and a human cell line expressing a nucleotide sequence encoding an antigen of EBV.

The inventions listed as Groups I to III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the technical features among different group of inventions are not same. For example, the group I is a composition and method for using the composition comprising one single cell line expressing an immunomodulatory gene and a nucleotide sequence encoding an antigen of EBV, whereas group II is directed to a composition and a method of using the composition comprising two cell lines, wherein one of them expresses a nucleotide sequence encoding an antigen of EBV and another expresses an EBV antigen. Group III differs from any of the group of inventions in that it is drawn to a composition and a method of using the composition comprising an immunomodulator and a human cell line expressing a nucleotide sequence encoding an antigen of EBV. Therefore, they lack of a common technical feature that link them together as one invention.

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2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species for an EBV antigen are as follows:

i). EBNA1, ii). LMP1 and iii). LMP2.

The species for an immunomodulatory gene are as follows:

1).  $\text{INF}\alpha$ , 2).  $\text{INF}\beta$ , 3).  $\text{INF}\gamma$ , 4). IL-1, 5). IL-2, 6). IL-3, 7). IL-4, 8). IL-5, 9). IL-6, 10). IL-7, 11). IL-8, 12). IL-10, 13). IL-12, 14). IL-20, 15).  $\text{TNF}\alpha$ , 16).  $\text{TNF}\beta$ , 17). MIP-1 $\alpha$ , 18). MIP-1 $\beta$ , 19). MIP-3 $\alpha$ , 20). MIP-3 $\beta$ , 21). RANTES, 22). HCC-1, 23). MIPF-1, 24). MCP\_1, 25). MCP-2, 26). MCP-3, 27). MCP-4, 28). MCP-5, 29). Eotaxin, 30). Tarc, 31). ELC, 32). I309, 33). GCP-2, 34). Gro- $\alpha$ , 35). Gro- $\beta$ , 36). Gro- $\gamma$ , 37). Nap-1, 38). Ena-78, 39). Gcp-2, 40). IP-10, 41). Mig-1, 42). I-Tac, 43). Sdf-1, 44). Bca-1, 45). A heat shock protein, 46). CpG, 47). Erythropoietin, 48). FLT-1 ligand, 49). M-CSF, 50). G-CSF and 51. GM-CSF.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. The claims are deemed to correspond to the species listed above in the following manner:  
species

Species i) to iii) are corresponding to claim 2. The following claim(s) are generic: claim 1-2 are generic.

Species of 1) to 51) are corresponding to claims 3-9. Claims 1-9 are generic.

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4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the species as claims are not obvious version each from other. One of the species IL-2 gene expression in a host cell line K562 that lacks of MHC-I and MHC-II and expresses EBV antigen as evidenced by Morishima et al. (J. Exp. Immunol. 1999, Vol. 115, pp. 385-392).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao Qun Li/

Primary Examiner, Art Unit 1648